Serial No.: 10/667,931 - 2 - Art Unit: 1612

Conf. No.: 1625

## In the Claims

- 1-86. (Cancelled)
- 87. (Currently Amended) A process for preparing a lipid suspension, the method comprising:
- (a) contacting at least two individual, <u>purified</u>, <u>phospholipids</u> [[lipids]] with a first non-aqueous solvent which causes the <u>phospholipids</u> [[lipids]] to dissolve and form a lipid solution, <u>wherein the contacting comprises the sequential addition of the at least two phospholipids to the first non-aqueous solvent, or combining the at least two individual phospholipids with each other prior to their addition to the first non-aqueous solvent;</u>
- (b) contacting the lipid solution with a second non-aqueous solvent which causes the lipids to precipitate out as a solid lipid blend;
  - (c) collecting the solid lipid blend;
- (d) contacting the solid lipid blend with a third non-aqueous solvent which causes the lipid blend to dissolve to form a lipid blend solution;
- (e) contacting the lipid blend solution with an aqueous solution to yield a lipid suspension.
- 88. (Previously Presented) The process of Claim 87, wherein each of the lipids has a gel to liquid crystalline phase temperature and wherein the lipid blend solution of step (d) is heated to a temperature that is about equal to or above the highest gel to liquid crystalline phase temperature of the lipids.
- (Previously Presented) The process of Claim 87, wherein the first non-aqueous solvent is a mixture of methanol and toluene.
- (Previously Presented) The process of Claim 87, wherein the second non-aqueous solvent is methyl t-butyl ether.

 (Previously Presented) The process of Claim 87, wherein the third non-aqueous solvent is selected from propylene glycol, ethylene glycol, and polyethylene glycol 300.

- (Previously Presented) The process of Claim 91, wherein the third non-aqueous solvent is propylene glycol.
- 93. (Previously Presented) The process of Claim 87, wherein the aqueous solution is water, saline, a saline and glycerin mixture, or a saline and glycerin and non-aqueous solvent mixture.
- (Previously Presented) The process of Claim 93, wherein the aqueous solution is a saline and glycerin mixture.
- 95. (Previously Presented) The process of Claim 93, wherein the aqueous solution is a saline, glycerin, and propylene glycol mixture.
- 96. (Previously Presented) The process of Claim 87, wherein the first non-aqueous solvent is a mixture of methanol and toluene and wherein the second non-aqueous solvent is methyl tbutyl ether.
- 97. (Previously Presented) The process of Claim 87, wherein the third non-aqueous solvent is propylene glycol and wherein the aqueous solution is a saline, glycerin, and propylene glycol mixture.
- 98. (Previously Presented) The process of Claim 96, wherein the third non-aqueous solvent is propylene glycol and wherein the aqueous solution is a saline, glycerin, and propylene glycol mixture.

99. (Previously Presented) The process according to Claim 98, wherein sodium chloride glycerin propylene glycol and about 0.75 to 1.0 mg/mL of the lipid blend are present in the lipid suspension.

- 100. (Previously Presented) The process according to Claim 87, wherein the third non-aqueous solvent is heated to a temperature of about 30 to 70°C prior to contacting with the solid lipid blend.
- 101. (Previously Presented) The process according to Claim 87, wherein the third non-aqueous solvent is heated to a temperature of about 50 to 55°C prior to contacting with the solid lipid blend.
- 102. (Previously Presented) The process according to Claim 87, wherein in step (d) the ratio of solid lipid blend to third non-aqueous solvent is from about 5 mg of solid lipid blend per mL of non-aqueous solvent to about 15 mg/mL of solid lipid blend per mL of non-aqueous solvent.
- 103. (Previously Presented) The process according to Claim 102, wherein the ratio of solid lipid blend to third non-aqueous solvent is about 10 mg/mL.
- 104. (Previously Presented) The process according to Claim 87, wherein in step (e), the aqueous solution is heated to a temperature of about 45 to 60°C prior to contacting with the lipid blend solution.
- 105. (Previously Presented) The process according to Claim 104, wherein the aqueous solution is heated to a temperature of about 50 to 55°C prior to contacting with the lipid blend solution.
- 106. (Previously Presented) The process according to Claim 89, wherein the lipid blend solution is heated to a temperature of at least about 67°C.

107. (Previously Presented) The process according to Claim 89, wherein step (d) of the process further comprises:

filtering the lipid blend solution through a sterilizing filter to form a filtered lipid blend solution.

108. (Previously Presented) The process according to Claim 107, wherein step (d) of the process further comprises;

filtering the filtered lipid blend solution through a second sterilizing filter to form a twice filtered lipid blend solution.

- 109. (Previously Presented) The process according to Claim 108, wherein the sterilizing filters are at a temperature of from about 70 to 80°C.
- 110. (Previously Presented) The process according to Claim 109, wherein  $0.2\mu m$  hydrophilic filters are used.
- 111. (Previously Presented) The process according to Claim 107, wherein the process further comprises:

dispensing the filtered lipid blend solution into a vial.

112. (Previously Presented) The process according to Claim 111, wherein the process further comprises:

exchanging the headspace gas of the vial with a perfluorocarbon gas.

- 113. (Previously Presented) The process according to Claim 112, wherein the perfluorocarbon gas is perfluoropropane.
- 114. (Previously Presented) The process according to Claim 113, wherein exchange of headspace gas is performed using a lyophilizing chamber.

- 115. (Previously Presented) The process according to Claim 112, wherein the process further comprises: sterilizing the vial.
- 116. (Previously Presented) The process according to Claim 115, wherein the vial is sterilized at about 126-130°C for 1 to 10 minutes.
- 117. (Previously Presented) The process of Claim 87, 88, 96, 97, 100, 102 or 104 wherein the lipids comprise:
  - (a) 1,2-dipalmitoyl-sn-glycero-3-phosphatidylcholine;
  - (b) 1,2-dipalmitoyl-sn-glycero-3-phosphotidic acid, mono sodium salt; and,
- (c) N-(methoxypolyethylene glycol 5000 carbamoyl)-1,2-dipalmitoyl-sn-glycero-3-phosphatidylethanolamine, mono sodium salt.
- 118. (New) The process of Claim 87, wherein
- (i) the purified phospholipids comprise:
  - (i') 1,2-dipalmitoyl-sn-glycero-3-phosphatidylcholine;
  - (i") 1.2-dipalmitovl-sn-glycero-3-phosphotidic acid, mono sodium salt; and,
- (i''') N-(methoxypolyethylene glycol 5000 carbamoyl)-1,2-dipalmitoyl-sn-glycero-3-phosphatidylethanolamine, mono sodium salt;
- (ii) the first non-aqueous solvent is a mixture of methanol and toluene;
- (iii) the second non-aqueous solvent is methyl t-butyl ether:
- (iv) the third non-aqueous solvent is propylene glycol;
- (v) the aqueous solution is water, saline, a saline and glycerin mixture, or a saline and glycerin and non-aqueous solvent mixture;
- (vi) the third non-aqueous solvent is heated to a temperature of about 30 to 70°C prior to contacting with the solid lipid blend:
- (vii) in step (d) the ratio of solid lipid blend to third non-aqueous solvent is from about 5 mg of solid lipid blend per mL of non-aqueous solvent to about 15 mg/mL of solid lipid blend per mL of non-aqueous solvent;

(viii) in step (e), the aqueous solution is heated to a temperature of about 45 to 60°C prior to contacting with the lipid blend solution;

- (ix) step (d) of the process optionally comprises filtering the lipid blend solution through a sterilizing filter to form a filtered lipid blend solution;
- (x) the process comprises dispensing the filtered lipid blend solution into a vial;
- (xi) wherein the process comprises exchanging the headspace gas of the vial with perfluoropropane; and
- (xii) the process comprises sterilizing the vial.
- 119 (New) The process according to Claim 118, wherein sodium chloride glycerin propylene glycol and about 0.75 to 1.0 mg/mL of the lipid blend are present in the lipid suspension.